

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

28-04

5/20/04

FSIS SAMPLE COLLECTION FROM CATTLE CONDEMNED DURING ANTE-MORTEM INSPECTION FOR THE BOVINE SPONGIFORM ENCEPHALOPHATHY (BSE) SURVEILLANCE PROGRAM

NOTE: FSIS PERSONNEL ARE NOT TO IMPLEMENT THE SAMPLE COLLECTION PROCEDURES IN THIS NOTICE UNTIL JUNE 1, 2004

I. PURPOSE

This notice contains updated information from FSIS Notice 18-03, dated 5/27/03. That notice expires on 6/1/04. In light of recent events, FSIS will be collecting brain samples from cattle at federally-inspected establishments for the purpose of BSE testing. Therefore, FSIS is issuing new sample collection, documentation, and shipping procedures to inspection program personnel, particularly Public Health Veterinarians (PHVs). Specifically trained FSIS PHVs will collect the brain samples. The samples will be shipped to the USDA Animal and Plant Health Inspection Service (APHIS) National Veterinary Services Laboratory (NVSL) in Ames, Iowa, or another APHIS-designated laboratory.

II. BACKGROUND

BSE is a reportable disease in the United States. In cooperation with FSIS, APHIS leads an ongoing, comprehensive, interagency surveillance program for BSE. Using the Federal Meat Inspection Act, 21 U.S.C. 603, part of the FSIS ante-mortem examination and inspection procedure will include the collection of a brain sample from cattle. For the first time, FSIS PHVs will collect brain samples from cattle that are condemned during ante-mortem inspection at federally-inspected establishments. The APHIS Area Veterinary Inspector-in-Charge (AVIC) will focus upon sample collection activities by APHIS at locations other than federally-inspected establishments (e.g., rendering operations and on-farm). FSIS PHVs will take samples from all cattle showing signs of

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T/A Inspectors; Plant Mgt; TRA;
ABB; TSC; Import Offices

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central nervous system (CNS) disorders, as well as the types of cattle that may be at higher risk for being infected with the agent believed to cause BSE, based, in part, on European data. These cattle, while at federally-inspected establishments, are under the control of FSIS and will have the brain sample collected either by the trained FSIS

PHV or an available APHIS technician with direct supervision and oversight by the FSIS PHV.

Under FSIS Notice 18-03 FSIS contacted APHIS whenever specific cattle were presented for ante-mortem inspection (e.g., cattle exhibiting CNS symptoms). The notice also stated that an APHIS veterinarian will be responsible for collecting the brain sample. When FSIS Notice 18-03 expires on June 1, 2004, APHIS will no longer collect the brain samples.

As instructed in this notice, FSIS personnel will collect brain samples from ante-mortem condemned cattle, and especially from any cattle exhibiting CNS symptoms, and will submit the samples to APHIS for analysis. APHIS will no longer collect brain samples at FSIS-inspected establishments.

III. Should the FSIS PHV have an awareness meeting with the establishment regarding the BSE testing process?

A. Yes, before June 1, 2004, the FSIS PHV needs to meet with the establishment to explain the procedure for the collection of brain samples for BSE testing. At this meeting, the FSIS PHV and management should discuss:

1. the FSIS procedures set forth in this notice.
2. how the establishment will ensure that ante-mortem condemned cattle will be segregated from other cattle,
3. whether the establishment will remove the head under the direct supervision of the FSIS PHV, or whether the FSIS PHV will have to remove the head,
4. whether the establishment has existing arrangements with APHIS under which the establishment delivers the carcass to deadstock facilities, renderers, or other animal disposition facilities so that APHIS can collect brain samples. If so, the FSIS PHV is to notify his or her District Office (DO).
5. how the establishment will hold the ante-mortem condemned animal (head and carcass) until removal from the premise,
6. how the establishment will dispose of the condemned carcass (i.e., picked up by renderer, sent to a landfill) and that the establishment is to maintain records, as required in 9 CFR 320.1, regarding the disposition of the condemned carcasses, and

7. that the establishment may obtain additional information about the sampling program from <http://www.aphis.usda.gov/lpa/issues/bse/bse.html>.

B. In a memorandum of interview, the FSIS PHV is to document who was present at the awareness meeting, the date and time of the meeting, what was discussed and decided regarding the issues above, and any documents that were shared with management.

C. The FSIS PHV is to maintain a copy of the memorandum of interview in the official government file, provide a copy to the plant management, and electronically mail a copy to the APHIS AVIC.

IV. Who, in FSIS, will collect the brain tissue sample?

Trained FSIS PHVs will collect the sample from ante-mortem condemned cattle. FSIS, along with APHIS, will sponsor a special sample collection training session prior to June 1, 2004. Most establishments with a history of having ante-mortem condemned cattle will soon have a trained FSIS PHV on-site. Other establishments, such as those in remote locations, may have a trained FSIS PHV come to the establishment to collect samples. Still, other establishments may have an APHIS technician on-site to collect samples. However, the APHIS technician will, for purposes of brain sample collection, collect the sample with direct supervision by the FSIS PHV.

V. What cattle will be sampled by FSIS for BSE surveillance purposes?

A. All ante-mortem condemned cattle at federally-inspected establishments will have a portion of the brain collected by the specially trained FSIS PHV, except for 1) cattle that are 400 pounds or less (which may be referred to as “veal calves”) with characteristics of immature cattle, condemned by the FSIS PHV but that do not exhibit CNS signs, and 2) cattle condemned on ante-mortem inspection that the establishment elects to have treated pursuant to 9 CFR 309.13(b).

B. The FSIS PHV or the APHIS technician under the supervisory authority of the FSIS PHV will collect the brain sample from cattle condemned by the FSIS PHV during ante-mortem inspection at the federally-inspected establishment. Cattle off-loaded from the transport vehicle onto the premises of the federally-inspected establishment, whether dead or alive, will be sampled by the FSIS PHV for BSE after the cattle have been condemned during ante-mortem inspection. In addition, cattle passing ante-mortem inspection but later found dead prior to slaughter will be condemned and be sampled by the FSIS PHV. The FSIS PHV is to make all final disposition decisions regarding whether cattle should be condemned in accordance with 9 CFR part 309.

VI. What information will the FSIS PHV maintain regarding the identity of condemned cattle?

The FSIS PHV will ensure the collection and documentation of all animal

identification associated with cattle condemned during ante-mortem inspection that are to be sampled by FSIS. The FSIS PHV is to attach the "U. S. Condemned" tag cattle condemned during ante-mortem inspection in accordance with 9 CFR 309.13. The FSIS PHV is to also ensure that available records associated with the documentation of the ownership of the cattle are maintained along with a file on each BSE-sampled animal. This documentation will facilitate trace back in the event that the sample result is positive for BSE. The documentation should include records in accordance with 9 CFR 320.1. **NOTE:** The slaughter establishment should not be considered the owner of the animal as a default. Once the brain sample has been collected from the head and all animal identification has been recorded and removed, the head and remainder of the animal are to be disposed of in accordance with 9 CFR 314. The establishment is to ensure that unsanitary conditions do not result from inappropriate holding of the head and carcass while the condemned material is awaiting pick-up by a renderer or by other means of transport or disposal.

VII. What is the process for ensuring that the condemned cattle (e.g., the carcass and head minus the brain sample) are removed from the establishment?

The FSIS PHV should ensure that unsanitary conditions are not created by the presence of the condemned cattle (9 CFR part 416). The establishment is responsible for the disposal of the condemned cattle in accordance with 9 CFR part 314. In cases in which the establishment cannot obtain transport services for removal of the condemned cattle in a timely manner, the establishment should contact the APHIS AVIC. Also, the establishment is to maintain records regarding the disposition of the condemned cattle in accordance with 9 CFR 320.1.

VIII. How will the cattle be handled in order for the FSIS PHV to collect the brain tissue sample?

A. If condemned cattle are alive, the establishment is required to humanely euthanize the cattle, in accordance with 9 CFR 309.13. The head should be removed as quickly as possible in order to collect the brain sample. If the establishment does not make arrangements to remove the head, the FSIS PHV should notify the Front-line Supervisor that the brain sample collection will need to be taken as a priority over other ante-mortem or post-mortem procedures.

B. The brain sample should be collected either in the inedible area of the establishment or other area set aside for such collection in which edible product cannot become adulterated due to the creation of an unsanitary condition. The establishment, APHIS technician, and FSIS personnel are to take proper sanitary measures before returning to edible areas of the establishment after brain sample collection, in accordance with 9 CFR 416.5.

IX. Will the FSIS PHV receive special sample boxes and instructions for shipping the sample?

A. Establishments with a history of high ante-mortem condemnation rates for slaughter will be identified by FSIS and the FSIS PHV at these establishments will receive multiple special sample boxes and shipping instructions from APHIS. Establishments without a history of high ante-mortem condemnation rates for slaughter will be identified by FSIS and the FSIS PHV at these establishments ultimately will receive sample boxes and shipping instructions from APHIS. The brain samples will be shipped to the APHIS NVSL or other designated laboratory, but not to an FSIS laboratory. (See Attachment 1).

B. After June 1, 2004, if cattle are condemned at ante-mortem inspection and the trained FSIS PHV does not have a special sample box and shipping instructions, the brain sample is to be collected by the FSIS PHV and put into a plastic bag and securely stored in a cooler (not a freezer). The sample is not to pass through or to be stored in areas of the establishment where edible product is produced. This may mean that the sample has to be stored under refrigeration outside of the official establishment. If there is no trained FSIS PHV or APHIS technician immediately available to collect the brain sample, the FSIS PHV should have the establishment save the head, brain intact, and place the head in a cooler (not a freezer) to reduce post-mortem autolysis of the brain. The head should be placed into a plastic bag and securely stored as explained above.

X. What is included in the special sample box and shipping instructions?

The special sample box from APHIS will include a sample collection kit (e.g., equipment to obtain the brain sample, a tube for placing the packaged sample within the shipping container, and identifying labels to affix to the sample). The FSIS PHV is to enter the "U.S. Condemned" tag number onto the APHIS-supplied forms. FSIS should record any APHIS identifying bar code labels onto the FSIS condemnation certificate. The shipping container will be picked up by FedEx, using the APHIS contract for overnight shipping. If there is a problem with the FedEx pickup of BSE samples, the FSIS PHV should contact the DO. The DO will contact the APHIS contact person responsible for the APHIS FedEx contract. **NOTE:** In situations where the last FedEx pick-up for the day has been missed or the sample is collected on a day when FedEx does not pick up, store the samples as discussed in paragraph IX. B. until the next available FedEx pick up day.

XI. What information will the FSIS PHV identify on the condemnation report and the APHIS sample request form?

The FSIS PHV will continue to complete the condemnation form, FSIS Form 6000-13, (Certification of Ante-mortem or Post-mortem Disposition of Tagged Animals) and FSIS Form 6150-1 (Identification Tag – Ante-mortem). The FSIS PHV should pay special attention when providing a full description of the reason for the condemnation on FSIS Form 6000-13 and fully fill out FSIS Form 6150-1 (i.e., identification, breed, sex,

reason for tag, and clinical signs). In addition, the FSIS PHV is to include similar information on the APHIS sample request form, including the estimated age of the cattle (see <http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=/ofo/tsc/index.htm>.)

The FSIS PHV should give special consideration to any age documentation that accompanies cattle to the federally-inspected establishment, in lieu of a dentition determination.

XII. How will sample results be reported?

APHIS NVSL will report the sample result to the establishment. FSIS is working with APHIS on a process to also include the FSIS PHV in the reporting of the sample result.

XIII. Will the FSIS PHV collect samples from healthy-appearing cattle that are not condemned?

The details regarding the testing of healthy appearing cattle 30 months of age and older by FSIS or APHIS is still under discussion. This group of cattle is much less likely to demonstrate BSE infectivity than those that show CNS symptoms or that have died on-farm or otherwise, or that are ante-mortem condemned. Thus, the details for the portion of the BSE surveillance program involving healthy-appearing cattle will issue in a separate FSIS notice at a later date.

XIV. What form will the FSIS PHV complete to record each sample taken?

The FSIS PHV will complete FSIS Form 5000-9, BSE Sampling Tracking Sheet located in *MS Outlook, Public Folders, All Public Folders, Agency Issuances, Forms, FSIS 5000 series* to report every sample collected. To facilitate APHIS reimbursement for the sample, the FSIS PHV will send a hard copy of the Form to the Financial Processing Center, Financial Management Division.

Refer questions to the Technical Assistance and Correlation Division, Technical Service Center at (402) 221-7400.

Philip S. Derfler /s/

Deputy Administrator
Office of Policy, Program, and Employee Development

Attachment 1

Designated Laboratories for BSE Sample Submission

State where sample was collected	Designated laboratory
Arizona, California, Nevada	California Animal Health and Food Safety Lab System University of California – Davis, CA
Colorado, Kansas, Missouri, Nebraska, North Dakota, South Dakota, Utah, Wyoming	Colorado State University Veterinary Diagnostic Lab Ft. Collins, CO
Arkansas, Louisiana, New Mexico, Texas	Texas Veterinary Medical Diagnostic Laboratory College Station, TX
Minnesota (or NVSL), Wisconsin	Wisconsin Animal Health Laboratory Madison, WI
Idaho, Montana, Oregon, Washington	Washington State University Animal Disease Diagnostic Lab Pullman, WA
Alabama, Florida, Georgia, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Virginia	Athens Diagnostic Laboratory, College of Veterinary Medicine University of Georgia; Athens, GA
Connecticut, Delaware, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Pennsylvania (all Pennsylvania), Rhode Island, Vermont	NY State College of Veterinary Medicine Veterinary Diagnostic Laboratory, Cornell University Ithaca, NY
Alaska, Hawaii, Illinois, Indiana, Iowa, Kentucky, Minnesota (or WI), Ohio, Puerto Rico, West Virginia	USDA, APHIS, National Veterinary Services Laboratory (NVSL) Ames, IA

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE	29-04	5-27-04
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QUESTIONS AND ANSWERS FOR FSIS NOTICE 28-04 REGARDING ANTE-MORTEM CONDEMNED CATTLE

I. PURPOSE

This notice provides clarification to FSIS Notice 28-04, FSIS Sample Collection From Cattle Condemned During Ante-Mortem Inspection for the Bovine Spongiform Encephalopathy (BSE) Surveillance Program. The following issues are addressed:

1. Expectations regarding the Animal and Plant Health Inspection (APHIS) arrangements, through the APHIS Area Veterinarian-in-Charge (AVIC), with establishments for APHIS to test condemned cattle at a central location,
2. Additional questions FSIS Public Health Veterinarian (PHV) should seek answers to either at the awareness meeting or at the on-going weekly meetings,
3. Why FSIS Notice 28-04 stated FSIS would not collect brain samples from cattle condemned on ante-mortem inspection that the establishment elects to have treated pursuant to 9 CFR 309.13(b),
4. A corrected form number for reimbursement associated with FSIS sample collections, and
5. Miscellaneous questions.

Also, this notice issues a revised list of the laboratories where PHVs are to send samples.

DISTRIBUTION: Inspection Offices;
T/A Inspectors; Plant Mgt; TRA;
ABB; TSC; Import Offices

NOTICE EXPIRES: 6-1-05

OPI: OPPED

II. QUESTION AND ANSWERS FOR EACH ISSUE

A. Issue 1. Expectations regarding the APHIS arrangements with establishments to test condemned cattle at a central location

Question: What controls does FSIS expect the establishment to have in place in order for FSIS to recognize an APHIS arrangement to have FSIS condemned cattle transported off-site from the establishment to an APHIS central sample collection point?

Response: FSIS will recognize such arrangements if establishments provide procedures for ensuring that the PHV will be notified that the condemned cattle are delivered to the APHIS central sample collection point for brain sample collection. The notification by the establishment provides information that is required under the recordkeeping requirements in 9 CFR 320.1. **NOTE:** Condemned cattle will continue to be denatured in the presence of an inspector at the establishment, and the U.S. Condemnation tag will be removed by the FSIS PHV. The FSIS PHV will not be able to close out the files on these condemned cattle, however, until notified by the establishment that these condemned cattle were delivered to the APHIS central sample collection point.

In order for the FSIS PHV to recognize the arrangement answers to the following issues should be provided:

1. The process for denaturing the cattle in a manner that would not affect the collection of a brain sample,
2. How the FSIS condemnation tag numbers (the tag are removed only by FSIS) will remain associated with the condemned cattle (this does not mean physically attached),
3. Who will remove the cattle from the establishment and transport it to the APHIS central sample collection point. (The transporter of the condemned cattle is to be registered with FSIS in accordance with 320.5),
4. The location of the APHIS central sample collection point, including the address and a contact at the location,
5. How the APHIS sample collection representative is made aware that FSIS condemned cattle are being delivered to the APHIS central sample collection point, and
6. How the establishment will provide notification to the FSIS PHV that the condemned cattle were delivered to the APHIS central sample collection point.

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Question 2: What will happen if an establishment that chooses to send condemned cattle to an APHIS central sample collection point fails to have or maintain appropriate procedures and documentation that demonstrates that the cattle were delivered and arrived at the APHIS central collection point?

Response: The failure of the establishment to ensure that condemned and denatured cattle are appropriately controlled, tracked, and delivered to the central collection point will result in the Agency no longer allowing condemned cattle to be removed from the premises for sampling and may be treated as a prohibited act, in violation of the Federal Meat Inspection Act, 21 U.S.C. 610, and the regulations that FSIS has adopted under 21 U.S.C. 603(a) and 9 CFR 314.9.

B. Issue 2. Questions that the (PHV) should ask the establishment management at the awareness meeting or at the on-going weekly meeting.

Answers to the following questions are necessary to better understand the establishment's identification and control procedures for dead cattle, non-ambulatory disabled cattle, and condemned ambulatory cattle:

For dead cattle

1. Does the establishment have arrangements with APHIS for off-site sample collection? (If yes see II. A. of this notice).
2. Will dead cattle be off-loaded at the official premises, or will they be transported to an APHIS central sample collection point?
3. If dead cattle are off-loaded in an establishment's holding pens, how will the cattle be segregated to provide for sample collection?
4. Has an appropriate area been designated for collecting the brain sample from condemned dead cattle?
5. Who will be removing the head of condemned cattle?
6. Has a procedure been established for containing the condemned cattle (and parts, including blood) during sample collection in order to prevent an insanitary condition?
7. Has a procedure been established to properly clean and sanitize the sampling area? **[NOTE:** Special cleaning and sanitization of pens and holding areas is not required; normal cleaning is sufficient.]
8. Will the sampled cattle (carcass and head) be held pending receipt of laboratory results, or, alternatively, how will the sampled cattle be disposed of? **[NOTE:** There is no requirement by FSIS to hold the sampled cattle after the brain sample has been collected. However, the establishment should contact the APHIS AVIC if there is a problem with the timely pick-up or removal of sampled cattle.]

For non-ambulatory disabled (live) cattle

1. Where will cattle be euthanized (e.g., in the establishment's holding pens or on the transport vehicle)? **[NOTE:** Condemned cattle must be euthanized at the establishment, under the supervision of FSIS, in order to ensure that the cattle are humanely handled. Condemned cattle cannot be removed from the establishment and euthanized at an APHIS central sample collection point. The establishment should ensure that the method of euthanization does not impact the quality of the brain sample (e.g., special low velocity 22 ammunition into the forehead of the condemned cattle would kill the animal, but would NOT damage the part of the brain for BSE sampling; a bigger shot would have the capacity to destroy more of the brain, possibly the brainstem, and would impact the quality of the brain sample).]

2. Are all provisions for handling dead cattle being followed?

For condemned ambulatory (live) cattle

Are all provisions for handling non-ambulatory disabled (live) cattle being followed?

C. Issue 3. Why FSIS Notice 28-04 stated that FSIS would not collect brain samples from cattle condemned on ante-mortem inspection that the establishment elects to have treated pursuant to 9 CFR 309.13(b).

Question: In the May 20, 2004 memorandum from the APHIS and FSIS Administrators regarding the BSE sampling of condemned cattle, there was no mention of an exemption from sampling for cattle being treated pursuant to 9 CFR 309.13(b). However, FSIS Notice 28-04, also dated May 20, 2004, does include the exemption (see Section V. A.). Which policy statement is applicable to FSIS?

Response: FSIS Notice 28-04 contains the procedures that FSIS inspection program personnel should follow. Although the memorandum from the Administrators did not specifically address this exemption, the exemption was already provided for in FSIS regulations and was not deemed necessary to include in the memorandum. A copy of the memorandum is attached.

D. Issue 4. Corrected form number for reimbursement associated with FSIS sample collections.

Question: What is the correct form number to be completed by FSIS in order to ensure that FSIS gets reimbursed by APHIS for brain sample collection?

Response: The corrected form number is FSIS Form 5000-11 (BSE Sampling Tracking Sheet). FSIS Notice 28-04 incorrectly listed the form number as FSIS Form 5000-9.

E. Issue 5. Miscellaneous questions.

Question 1: Do cattle have to be presented for ante-mortem inspection in order

to be subject to sample collection?

Response: All cattle that are off-loaded from transportation vehicles are considered to be presented for inspection and, therefore, are to be test under FSIS Notice 28-04, where applicable. Dead cattle that are off-loaded to facilitate the off-loading of live animals, but that will be re-loaded onto the transport vehicle, are not subject to sampling by FSIS.

Question 2: Is the PHV responsible for determining whether the sample is of acceptable quality, (i.e., whether autolysis has not occurred), before submitting a sample to the laboratory?

Response: The PHV is not responsible for making these determinations. All samples are to be taken and submitted to the laboratory.

Question 3: Can PHVs get rabies vaccinations?

Response: Yes, however rabies vaccinations are voluntary. Only PHVs who are actually involved with BSE sample collection will be eligible for reimbursement on the vaccination series. PHVs should make arrangements for the vaccinations with their private physician. PHVs should contact their Front-line supervisor for approval on reimbursement prior to beginning the three shot vaccination series.

Philip S. Derfler /s/

Assistant Administrator
Office of Policy, Program, and Employee Development

{See Page 21 of Procedure Manual for Bovine Spongiform Encephalopathy (BSE) Surveillance for updated listing of designated laboratories.}

Attachment

Designated Laboratories for BSE Sample Submission

State where sample was collected	Designated laboratory
Arizona, California, Nevada	CAHFS-Thurman Bldg. West Health Science Drive UC Davis Davis, CA 95616
Colorado, Kansas, Missouri, Nebraska, North Dakota, South Dakota, Utah, Wyoming	Dr. Barbara Powers CO State University Vet Diagnostic Laboratory Ft. Collins CO 80523
Arkansas, Louisiana, New Mexico, Texas	Texas A & M TVMDL Pathology Department 1 Sippel Road College Station, TX 77843
Minnesota (or NVSL), Wisconsin	Dr. Phil Bochsler WVDL - TSE Laboratory 6101 Mineral Point Rd. Madison, WI 53705
Idaho, Montana, Oregon, Washington	Washington State University WADDL Animal Disease Diagnostic Laboratory Bazzler Bustad Hall Room 155-N Pullman WA 99164-7034
Alabama, Florida, Georgia, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Virginia	Athens Diagnostic Laboratory College of Vet Med Doris Miller University of Georgia Athens, GA 30602
Connecticut, Delaware, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Pennsylvania (all Pennsylvania), Rhode Island, Vermont	Cornell University Animal Health Diagnostic Laboratory Department of Biomedical Sciences S2-124 Schurman Hall Ithaca, NY 14853
Alaska, Hawaii, Illinois, Indiana, Iowa, Kentucky, Minnesota (or WI), Ohio, Puerto Rico, West Virginia	USDA, APHIS, National Veterinary Services Laboratory (NVSL) Ames, IA



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

J.L. Whitten Bldg. 312E
1400 Independence Ave.
Washington, D.C. 20250

MEMORANDUM FROM THE ADMINISTRATORS

FROM:

W. Ron DeHaven
Administrator
APHIS

W. R. DeHaven

MAY 20 2004

Barbara Masters
Acting Administrator
FSIS

Barbara Masters

MAY 20 2004

TO:

VSMT
Regional Directors/AVICs
Veterinary Services
District Managers
Field Operations

SUBJECT: Policy statement regarding BSE sampling of condemned cattle at slaughter plants – for immediate implementation.

This notice serves as follow-up guidance to the joint memo of May 5, regarding BSE surveillance sampling at slaughter plants. These enhanced procedures will be effective June 1, 2004:

FSIS will collect samples for BSE testing from cattle at federal establishments as described below:

- All cattle – regardless of age, including veal calves - condemned by FSIS upon antemortem inspection for CNS impairment will be sampled for BSE by FSIS personnel. Of the cattle condemned every year, approximately 300 are condemned for signs of CNS impairment.
- All cattle – with the exception of veal calves – condemned by FSIS upon antemortem inspection for any reason other than CNS will be sampled for BSE by FSIS personnel.
- APHIS will coordinate with the FSIS State Liaison Director to assist in assuring sample collection from State-inspected facilities.
- FSIS (or the state inspector where applicable) will collect brain tissue samples from dead cattle that arrive and are offloaded on the premises of FSIS-inspected establishments.

Furthermore:

- APHIS will obtain samples from animals that are dead on arrival –but not offloaded -- through their routine sampling and agreements with deadstock facilities, renderers, and other animal disposal facilities.



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MEMORANDUM FROM THE ADMINISTRATORS

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- In cases where APHIS has funded a technician to remain on the premises and take samples at FSIS-inspected establishments, that technician is under the oversight of the FSIS inspector-in-charge.
- FSIS and APHIS will work with plant management to ensure appropriate arrangements for removal or disposal of carcasses from sampled animals.
- FSIS and APHIS will consider alternative arrangements to test all cattle described above. Such arrangements may make use of previously established arrangements with deadstock facilities, renderers and other animal disposal facilities. These arrangements must include verification and documentation that cattle are sampled.
- USDA will establish a toll-free number for USDA employees and farmers/industry to call if they have any question or concern about BSE sampling. Calls will be routed to the appropriate APHIS Area Veterinarian in Charge for appropriate and timely follow-through, and AVIC's will be responsible for immediately elevating any issues that may potentially indicate a broader systemic problem. AVICs are also responsible for alerting the appropriate FSIS District Manager regarding any issues of joint concern.

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

33-04

6-14-04

COMPLIANCE AND INVESTIGATIONS DIVISION (CID) PROTOCOL FOR OFF-SITE COLLECTION OF BRAIN SAMPLES FOR BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) TESTING

I. PURPOSE

This notice issues the protocol for CID inquiries related to the sample collection of brain samples for BSE testing of bovine animals that were "U.S. Condemned" on ante-mortem inspection at federally-inspected establishments and moved from the federally-inspected establishment to an off-site sample collection location (See FSIS 28-04 and 29-04). The sample collection locations are typically rendering operations, 3D/4D operations, landfills, collection sites, pet food manufacturers, and other non-federally inspected establishments or locations. The Animal and Plant Health Inspection (APHIS) Area Veterinarian-in-Charge (AVIC), APHIS technician or APHIS contractor will collect the brain sample. The purpose of the protocol is to verify that ante-mortem condemned cattle arrive at the locations and the Animal and Plant Health Inspection Service (APHIS) is aware of the cattle's arrival.

II. VERIFICATION OF REGISTRATION

Program Investigators (PIs) are to inquire if the subject firm has completed FSIS Form 5020-1, Registration of Meat and Poultry Program Handlers, in compliance with 9 CFR 320.5, and as further described in FSIS Notice 27-04 dated May 17, 2004. If the subject firm is not registered, the PI should give a copy of the form to management. The name of the management official that was presented the form and the date are to be recorded in the PI Daily Activity Report (DAR).

III. NOTIFICATION

The appropriate CID Regional Manager (RM) will be notified by the District Office of establishments that have an agreement with APHIS for the off-site sample collection of brains. The CID RM will notify the appropriate District Manager if condemned carcass does not arrive at the off-site sampling location.

IV. PROCEDURES FOR RECORDING OFF-SITE SAMPLE COLLECTION

DISTRIBUTION: Inspection Offices;
T/A Inspectors; Plant Mgt; TRA;
ABB; TSC; Import Offices

NOTICE EXPIRES: 7-01-05

OPI: OPPED

LOCATIONS INTO THE PLANNED COMPLIANCE PROGRAM (PCP)

PIs are to record all off-site sample collection locations they visit as status code "B" in the Planned Compliance Program (PCP). They are to assign the sample collection location a primary business code "14" if no other type of business is conducted at the location. If the location conducts any other type of business, the PIs are to assign the appropriate business code as found under Appendix B in the Compliance Officer Manual and assign business code "14" as the secondary code. PIs are to complete the remaining inquiry and PCP documentation in the following manner:

A. Meeting with APHIS AVIC, Technician, or Contractor:

1. Conduct an entrance conference with the APHIS AVIC, technician, or contractor assigned to collect brain samples from FSIS ante-mortem condemned animals received from federally inspected establishment. Identify yourself, explain the purpose of your visit, and answer questions as they relate to the sampling initiative,

2. Review and discuss the procedures conducted when condemned cattle are delivered, and how APHIS is notified that the condemned cattle have arrived.

Seek answers to such questions as:

- a. How does the firm prepare the condemned cattle for sampling?

- b. How many hours per day and days per week are the sample collectors at the location, and are there times when a carcass would have to be held at the location because there was no sample collector available?

3. Discuss sampling procedures conducted by the APHIS AVIC, technician, or contractor.

B. Meeting with Off-Site Sample Collection Point Plant Management:

1. Conduct an entrance conference with management and identify yourself. Explain the purpose of your visit and answer questions.

2. Discuss the certification that the firm has from APHIS for receiving ante-mortem condemned cattle from federally inspected establishments and collecting samples.

3. Discuss the agreement that the firm has with the federally inspected establishments for receiving FSIS ante-mortem condemned cattle and collecting samples.

4. Discuss procedures that the firm conducts when receiving condemned cattle, preparing cattle for sampling, disposition of cattle after being sampled.

5. Document the registration status of the firm.

C. Facility Observations:

1. Observe and record the area set aside for collection of brain samples and carcass disposition area.

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2. Conduct a physical observation of cooler for storing brain samples (*if available*).

D. Examine or Observe Handling of Condemned Cattle, Storage, and Shipping Practices:

1. Observe U.S. condemned cattle received from federally inspected establishments that will be sampled for BSE.
2. Observe the proper disposal of the condemned carcass and parts after it has been sampled.

E. Records Review:

Review all records for completeness and accuracy (i.e., receiving records, ownership and trace-back records, laboratory forms, fed-ex air bills, sample results, APHIS records, etc.). During initial reviews, it will be important to capture all salient documentation in the PCP for future use.

F. Exit Meeting with the APHIS AVIC, Technician, or Contractor and Off-Site Sample Collection Point Management:

1. Conduct exit conferences with the APHIS AVIC, technician, or contractor and the off-site sample collection point management. The PI should decide whether to do this jointly or independently based on his or her observations and sound reason.
2. Ask questions to clarify observations.
3. Discuss findings.
4. Provide the APHIS technician or contractor and collection point management the opportunity to ask questions.
5. Advise them that a PI may conduct follow-up visits.

If the PIs have concerns about the sample collection activities he or she is to note this in the PCP and contact the RM if necessary.

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UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

40-04

7/29/04

ADDITIONAL BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) SURVEILLANCE SAMPLING QUESTIONS AND ANSWERS

The Food Safety and Inspection Service (FSIS) is issuing this notice to provide answers to questions FSIS personnel have asked regarding FSIS' BSE surveillance sampling program.

I. Electronic Animal Disposition Reporting System (eADRS) and Performance- Based Inspection System (PBIS)

A. Question: What does an FSIS Public Health Veterinarian (PHV) document in eADRS when *non-ambulatory disabled* cattle are euthanized at the election of the establishment? Examples would be when the plants humanely euthanize an animal prior to the arrival of a PHV, or when an animal becomes non-ambulatory after antemortem inspection has been conducted?

Answer: In such cases, the antemortem disposition would be "dead," and the PHV records this in eADRS under "deads." The category "non-ambulatory (plant condemned)" is no longer available for cattle in eADRS. Also, in such cases, the PHV may write "Dead (Plant rejected and euthanized)" in the "Diagnosis/Condition" column of FSIS Form 6000-13, Certificate of Antemortem or Postmortem Disposition of Tagged Animals.

B. Question: Does the PBIS system schedule the brain sample collection for BSE testing?

Answer: No. FSIS personnel collect samples in accordance with FSIS Notices 28-04 and 29-04.

DISTRIBUTION: Inspection Offices;
T/A Inspectors; Plant Mgt; TRA;
ABB; TSC; Import Offices

NOTICE EXPIRES: 8/01/05

OPI: OPPED

II. Alternative Sampling -- Animal and Plant Health Inspection Service (APHIS) Central Sample Collection Point

A. Question: What are the animal identification collection and documentation procedures for cattle sampled under an accepted “alternative program” (APHIS central sample collection point)?

Answer: Normal documentation procedures apply, including recording the condemned tag number and all animal identification (e.g., eartag, backtag) on FSIS Form 6150-1 (Identification Tag-Antemortem). However, in this case the animal identification tags or devices will remain on the animal or handled in accordance with an accepted alternative method. Condemned tags should be removed prior to transport and after the carcass has been denatured in accordance with 9 CFR 314.

B. Question: What responsibility does the FSIS PHV have to provide information to plant management for cattle sampled under an acceptable alternative program (APHIS central sample collection point)?

Answer: The FSIS PHV's responsibility is to supply plant management with copies of FSIS Form 6000-13, Certificate of Antemortem or Postmortem Disposition of Tagged Animals, that includes the condemned tag number. The establishment may also request to make copies of FSIS Form 6150-1. The establishment may use this information to fulfill the expectation of FSIS Notice 29-04 concerning alternative programs to ensure that the animal identification information and condemned tag number (although not physically attached) remain associated with the animal.

III. State, Talmadge-Aiken (T/A), and Custom-Exempt Establishments

A. Question: How is the sampling handled at T/A plants?

Answer: FSIS will perform sampling in TA plants. If sample collection is needed, the state coordinator should contact the District Office (DO).

B. Question: How is the sampling handled at State plants?

Answer: State plants should contact the State Area Veterinarian-in-Charge (AVIC) for sample collection. Any alternative programs for sampling off-premises must be consistent with FSIS Notice 29-04.

C. Question: At federally-inspected establishments, who is responsible for collecting brain samples from animals designated “for custom slaughter” and that are non-ambulatory disabled cattle or cattle that exhibit Central Nervous System (CNS) signs?

Answer: When an establishment's schedule of operations indicates that the establishment is operating under custom exempt, those animals are exempt from the inspection requirements of the Federal Meat Inspection Act (FMIA). Because custom exempt cattle that are non-ambulatory disabled or that exhibit CNS signs are unfit for food, inspection program personnel who observe cattle with these signs being

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slaughtered for food are to detain the carcass and head in accordance with FSIS Directive 8410.1, rev 2. Inspection program personnel also are to contact the DO.

The DO will assign a PHV to collect and submit a brain sample for BSE testing. In addition, the PHV is to notify the OPEER Regional Manager through supervisory channels.

IV. Sample Collection

A. Question: How will personnel be dispatched to collect samples at federally-inspected establishments?

Answer. District Managers will handle this within their districts according to staffing needs.

B. Question: Does the PHV have to be present when the head is removed?

Answer: While it is preferable that the PHV be present at the time of head removal, some situations (e.g., non-ambulatory disabled cattle that have been euthanized by the plant) may require removal of the head prior to the arrival of a PHV. The process for removal, storage, and control of the head and carcass denaturing should be decided during the awareness meeting with plant personnel if it is anticipated that removal of the head in the absence of the PHV may be necessary. The establishment's process should also ensure that sufficient controls are in place to maintain the identity of the animal.

C. Question: Are instruments used only to harvest the sample required to be sanitized?

Answer: No, but thorough washing is recommended. It would be preferable that dedicated or disposable instruments be used to harvest samples for BSE testing.

D. Question: How is the determination made that the animal is 400 lb. or less?

Answer: The PHV must rely on his or her judgment, expertise, or any other resources (e.g., records or actual weighing of animal) to determine the approximate weight of the animal.

E. Question: Are dead calves (i.e., less than 400 lbs.) sampled?

Answer: No, because such animals are not part of the high-risk population identified by APHIS.

F. Question: Who is responsible for sampling dead cattle off-loaded onto plant-owned property that is adjoining to, but not considered part of, the "official premises"?

Answer: Such cattle would be subject to sampling by APHIS.

G. Question: What is considered to be “presented for antemortem inspection”?

Answer: Live cattle that are off-loaded from transportation vehicles are considered to be presented for inspection and, therefore, are to be tested under FSIS Notice 28-04, where applicable. Dead cattle that are off-loaded to facilitate the off-loading of live animals, but that will be promptly re-loaded onto the transport vehicle, are not subject to sampling by FSIS.

H. Question: Does the head always have to be removed when harvesting samples?

Answer: PHVs have been trained to remove the head in order to collect the sample. If a plant is exposing the brain stem for sample collection by the PHV, the PHV will determine whether a sample can be adequately collected. Although PHVs can work with the plant to determine other efficient and suitable methods, decisions on the adequacy of sample collection procedures are the responsibility of the PHV.

I. Question: How is BSE sampling handled at small plants where there is no PHV?

Answer: The PHV responsible for final disposition in that plant should be contacted. If the animal is condemned, the DO will follow its procedures for arranging for sample collection by a trained PHV.

J. Question: What procedures should be followed for head removal after an animal is U. S. condemned and euthanized?

Answer: It is recommended that the establishment remove the head for FSIS sampling as soon as possible. FSIS sampling (including head removal if not performed by the establishment) may take precedence over other antemortem or postmortem procedures.

K. Question: Can the plant use the suspect pen for sampling?

Answer: The plant can use the suspect pen, provided humane handling and inspection of other animals in the suspect pen is not affected. Regardless of where the sampling is performed, sanitary conditions must be maintained.

V. Carcass Disposal

A. Question: If the plant takes the carcasses to a landfill, whose jurisdiction does this fall under?

Answer: This will be the responsibility of state or local authorities. FSIS personnel need only verify through plant records that the carcasses did in fact go to the landfill.

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B. Question: Can the establishment dispose of the carcass prior to receiving lab results?

Answer: Yes. Because the animal was condemned at antemortem inspection, there is no requirement for establishments to hold carcasses. FSIS is recommending that establishments make arrangements to confirm negative results prior to these carcasses being rendered. This would not be an issue for carcasses going to incineration, alkaline digestion, or a lined landfill. Also, local sanitary codes are applicable.

C. Question: Can establishments remove carcasses from the premises outside of the official hours of operation without being sampled?

Answer: Yes. There are no regulations which would prohibit this from occurring. However, establishments remain subject to the FMIA denaturing requirements for such carcasses (21 USC 641). FSIS is committed to sample all available carcasses during established hours of operation.

VI. Sample Integrity

A. Question: Is the PHV responsible for determining whether the sample is of acceptable quality (i.e., whether autolysis has not occurred) before submitting a sample to the laboratory?

Answer: The PHV is responsible for the timely collection of and proper shipping of collected samples to the laboratory. PHVs are not responsible for making the determinations about the quality of the collected samples for their diagnostic suitability. If the collected samples have to be held prior to shipping they are to be held in cold storage, not frozen.

B. Question: When extracting the brain stem, what distance above and below the "V" (obex) do you allow?

Answer: The cut should be made approximately ½ to 1 inch above and below the obex.

C. Question: If the obex is unavailable, is there any other tissue which can be submitted for testing?

Answer: No, the obex is the only location we are currently testing.

D. Question: Can the obex be moistened to facilitate its entry into the tube?

Answer: No.

E. Question: Should the sample be washed/rinsed to remove blood clots?

Answer: No. APHIS prefers that blood clots are removed by hand and the sample be blotted with a paper towel.

F. Question: Is it necessary to attach an FSIS security seal to sample?

Answer: No.

G. Question: Because samples cannot be stored or passed through areas in which there is edible product, how can establishments store these samples?

Answer: Plants may have a dedicated refrigerator for samples in the inspection office or elsewhere that can be reached without passing through edible areas. Different options should be discussed during the awareness meeting, and could include, for example, use of a portable cooler.

H. Question: What if the brain stem is mutilated due to the method used to euthanize the animal?

Answer: Submit the sample and write on the sample form that the sample was mutilated prior to collection.

VII. Laboratory Results

A. Question: How long does it take to receive results after the brain sample is submitted?

Answer: The laboratories generally report the results 36 to 48 hours after the sample is shipped.

B. Question: Who will receive the results?

Answer: A report of the test results will be sent to the submitter, the AVIC, and the establishment, if requested.

C. Question: Will the results of the BSE test be posted on Laboratory Electronic Application for Results Notification (LEARN)?

Answer: No, not at this time.

D. Question: Other than reporting positive results, what will the laboratory report state?

Answer: The laboratory report may state one of the following: “**Not Detectable**” which indicates that the sample was tested and the results were negative; “**Location**” which could mean that the sample appeared to be a brain stem, but could not be identified as the obex; or “**Not Tested**” or “**Not Testable**” which means that the sample could not be recognized as a brain stem or that it was autolyzed.

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E. Question: How may a carcass be disposed of when a result of “Not Tested” or “Not Testable” is received?

Answer: If a test was not conducted, plants may dispose of such carcasses by any available means such as inedible rendering, incineration, alkaline digestion, or movement to lined landfills in accordance with state or local codes.

VIII. Documentation

A. Question: What if the name and address of the owner are not available at the time of sampling?

Answer: The sample should be collected and submitted as soon as possible. The missing information can be sent at a later date when it becomes available (this information should be sent regardless of whether the sample results are positive or negative). This information should be made available in accordance with the recordkeeping requirements in 9 CFR part 320.

B. Question: Is it sufficient to identify a broker or auction house as the owner of the animal?

Answer: Every attempt should be made to attain the actual producer’s name and address. However, if that cannot be obtained, identify a broker or auction house as the owner.

C. Question: Is filling out FSIS Form 6000-13 mandatory?

Answer: No. For antemortem condemned cattle, complete FSIS Form 6000-13 when requested by plant management. Consistent with their training for collection of BSE samples, PHV’s are to maintain a file on each sampled animal. PHVs can use either a Form 6000-13, 6200-14, or 6150-1 to capture the condemnation Z-tag number of sampled animals. For plants with alternative procedures for off-site sampling, FSIS Form 6000-13 may be requested to facilitate correlations with the condemnation Z-tag number.

D. Question: Should animal identification (e.g., eartags, backtags) be collected and saved until sample results are received?

Answer: Yes, they should be saved in a plastic bag in association with the dedicated file. Do not send these items with the sample.

E. Question: How should “deads” be recorded in the “Clinical Signs” section of the APHIS form, Veterinary Services (VS) Form 10-4 - Supplemental Form?

Answer: Check the box marked “other” at the bottom-right portion of this section, and write in “dead” below it.

F. Question: Is the barcode placed on the copy of the condemnation form, or on the original?

Answer: On the copy (second sheet) that is maintained by FSIS. The original goes to the establishment.

G. Question: Is it mandatory to complete FSIS Form 5000-11, BSE Sampling Tracking Sheet?

Answer: Use of FSIS Form 5000-11 by PHVs who collect BSE samples is mandatory. The only acceptable version of this form is in Form Flow. The form is only to be used when FSIS personnel actually collect the sample. PHVs are to provide complete and accurate entries of all items on FSIS Form 5000-11. PHVs are to indicate the appropriate age to the best of their abilities. The forms should be either mailed or faxed to the Financial Processing Center (FPC). PHVs are not to submit duplicates because this would require FPC to verify the forms twice. Whether by mail or fax, PHVs can submit Form 5000-11 to the FPC on weekly basis. The form does not have to be submitted daily. Also, the PHV is not to submit other forms (e.g., FSIS Form 6000-13 or VS Form 10-4) to FPC. PHVs that collect a sample during a reimbursable overtime period are to note this in the provided check box, not in the remarks section. Established forms or timesheets should continue to be completed for regular and overtime hours.

H. Question: Should a copy of FSIS Form 5000-11 be sent with the sample?

Answer: No.

I. Question: Can unused sets of barcodes be utilized at a later date?

Answer: Yes, unused entire sets of barcodes can be utilized for future samples. Since each set represents a unique number, use one set of barcodes for each sample. Do not use incomplete sets. Destroy incomplete sets.

IX. Sample Shipping

A. Question: If a sample is collected on a Saturday, Sunday, or holiday, should the sample be held?

Answer: Yes, the sample should be held until the next available Federal Express pick-up.

B. Question: When a sample is sent, will the laboratory automatically return the shipping container?

Answer: National Veterinary Services Laboratory (NVSL) will automatically return the shipping container. However, the other labs do not provide automatic returns.

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Therefore, sufficient sampling supplies should be maintained by ordering through NVSL (Ames, IA).

C. Question: Should unused tubes be saved?

Answer: Yes. They can be used for subsequent sampling.

D. Question: What is the turnaround time on shipping containers sent to NVSL?

Answer: Approximately five days. In an emergency, APHIS can ship overnight.

E. Question: Are the fax forms available for requesting overnight delivery of shipping containers?

Answer: Yes. This form (BSE Kit and Instrument Order Form) is available on Outlook "All Public Folders/OFO/Technical Service Center/BSE Training Info."

F. Question: Can the same shipping container for samples from 2 different establishments be used?

Answer: Yes, as long as the paperwork and equipment (e.g., tubes) are separate and properly identified.

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